



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,815	12/07/2000	Akira Aomatsu	5836-01-MJA	5030
7590 Charles W Ashbrook Warner Lambert Company 2800 Plymouth Road Ann Arbor, MI 48105		09/21/2007	EXAMINER KWON, BRIAN YONG S	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 09/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Supplemental  
Notice of Allowability**

Application No.

09/674,815

Examiner

Brian S. Kwon

Applicant(s)

AOMATSU, AKIRA

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Appeal Brief.
2. ☒ The allowed claim(s) is/are 35-38 and 40.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20070622.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

BRIAN-YONG S. KWON  
PRIMARY EXAMINER

Art Unit: 1614

### DETAILED ACTION

1. This supplemental Action replaces the previous Notice of Allowability mailed 07/23/07. This Action is being issued to correct the incorrect dependency of original claim 40 (now claim 5) on cancelled claim 34.

### EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul M. Misiak on June 18, 2007.

The application has been amended as follows:

#### In the Specification:

In the first sentence(s) of the Specification, add --This application is a 371 of PCT/US99/10190 filed 05/10/1999 which claims a benefit of JAPAN 133113/98 filed 05/15/1998--.

#### In the Claims:

In claim 35, line 1, delete [The composition of Claim 34] and replace with --A solid pharmaceutical composition comprising: (a) a neutral  $\alpha$  amino acid, (b) a compound selected from the group consisting of gabapentin and pregabalin, and (c) optionally, one or more auxiliary agents--.

In claim 35, line 2, delete [selected from] and replace with --selected from the group consisting of--; and line 18, delete [and citrulline, and the D- and DL-forms thereof] and replace with --citrulline, and the D- or DL-forms thereof--.

Art Unit: 1614

In claim 36, line 2, delete [selected from] and replace with --selected from the group consisting of--; and line 6, delete [and] before "DL-forms thereof" and replace with --or--

In claim 37, line 1, delete [Claim 34] and replace with --Claim 35--; and lines 2-3, delete [the 4-amino-3-substituted-butanoic acid derivative] and replace with --the compound--.

In claim 38, line 1, delete [Claim 34] and replace with --Claim 35--; and line 1, delete [4-].

In claim 40, delete [Claim 34] and replace with --Claim 35--.

Claim 34 is cancelled.

#### *Reasons for Allowance*

2. The following is an examiner's statement of reasons for allowance: The prior art reference(s) alone or in combination (Robson et al., Coasta et al. and/or Bays et al.) in which the rejection of record is relied upon fail(s) to teach or suggest the superior unexpected results of the addition of the specific alpha amino acid recited in the instant claim 35 on the stability of gabapentin and pregabalin in reducing formation of lactam (lactamization).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### *Conclusion*

3. Claims 35-38 and 40 are allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Art Unit: 1614

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon  
**Primary Patent Examiner**  
**AU 1614**

A handwritten signature in black ink, appearing to read 'Brian', followed by a long horizontal flourish line.